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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,050	10/30/2003	Orhan Soykan	P-10120.00	1185

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EXAMINER	
WINAKUR, ERIC FRANK	
ART UNIT	**PAPER NUMBER**
3768	
MAIL DATE	**DELIVERY MODE**
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,050	SOYKAN ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 August 2007 has been entered.

Claim Objections

3. Claim 1 is objected to because of the following informalities: it appears that the term "contains" (line 6) should read "containing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 10 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As claim 1 identifies the analyte as troponin, claims 10 and 39 are not further limiting.

Claim Rejections - 35 USC § 103

5. Claims 1 - 8, 10, 11, 13 - 16, 18 - 21, and 33 - 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Van Antwerp et al. and Wicks et al. Chick et al. teach a method and arrangement for detecting an analyte in the

human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them (col. 2, line 31 - col. 6, line 44). Further, a drug delivery system in communication with the analyte detector may be implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold (col. 6, lines 1-5). The illuminating energy is visible light at a wavelength of 472 nm (col. 11, lines 36-47) and the analyte measured may be a protein in the blood (the level of which may vary under certain physiological states) or an antigen or a narcotic such as cocaine or heroin (col. 5, lines 15-50). Chick et al. teaches an implantable sensor with transdermal determination of analyte concentrations (column 6, lines 6 - 34; column 16, line 23 - column 17, line 32). Van Antwerp et al. (Figure 6 and the description thereof) teach an alternate arrangement that includes completely implantable emitter, detector, and sensing elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to use a completely implantable arrangement, as taught by Van Antwerp et al., since this is merely an alternate equivalent expedient.

Chick et al. in view of Van Antwerp et al. teach all of the features of the invention except that the sensed protein is troponin. Wicks et al. teach that troponin I is a protein that is a marker for cardiac damage (column 1, lines 24 - 41). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Chick

et al. with sensitivity for troponin, since Chick et al. teach that their method and arrangement are suitable for detecting proteins in the blood that are indicative of physiological states (column 9, line 59 - column 12) and Wicks et al. teach that troponin I is a blood protein that is a marker for cardiac damage.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Van Antwerp et al. and Wicks et al. as applied to claim 1 above, and further in view of Khaw et al. The combination teaches all of the features of the claimed invention except that the sensed protein is troponin-T antigen. Khaw et al. teach that troponin I and T are alternate equivalents for sensing heart attack related events (paragraphs [0002] and [0011]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to sense troponin T, since Khaw et al. teach that this is an alternate equivalent expedient to troponin I and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Van Antwerp et al. and Wicks et al. as applied to claim 11 above, and further in view of Kwon. The combination teaches all of the features of the claimed invention except for the particularly claimed fluorescent dyes. Kwon teaches monitoring analyte concentrations in the body using FRET, wherein one of the dyes which may be used is tetramethylrhodamine isothiocyanate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use with the FRET system disclosed by the combination with the fluorescent dye tetramethylrhodamine

isothiocyanate, since Kwon teaches that this dye allows for effective FRET analyte concentration measurements.

8. Claim 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Van Antwerp et al. and Wicks et al. as applied to claim 11 above, and further in view of Rao et al. The combination teaches all of the features of the claimed invention except that there is an alert module. Rao et al. teach an alternate FRET system that includes an alert module to notify a subject of changes in concentration (see Figure 9 and the description thereof). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include an alert module, as taught by Rao et al., since this allows a subject to be notified of changing concentrations.

Response to Arguments

9. Applicant's arguments filed 30 August 2007 have been fully considered but they are not persuasive. Applicant argues that while Chick teaches that a FRET detection system may be used to detect a protein, this "does not lead to the conclusion that one skilled in the art can modify any antigen with a FRET detector and that it still will be useful." Applicant alleges that one of skill in the art would not be able to reasonably predict whether after modification of the antibody with the FRET detector that the antibody would still bind the antigen; would not understand if the necessary distances between the detectors would even be possible for a cardiac troponin sensor; and that actual experimentation would be required to assess these concerns. Examiner notes that Applicant merely provides allegations without providing any evidence. Mere

allegations are not sufficient to overcome the *prima facia* showing of the prior art including the fact that Chick provides a detailed description of FRET, indicates that it is compatible with numerous analytes, and provides several embodiments to allow proper interaction between the two detectors. If Applicant's alleged difficulties actually existed, one would expect that Chick would have encountered some of them, noted these problems, and described solutions to any more limited embodiments that were found to overcome the alleged problems. That Chick was not required to overcome the alleged problems is a further indication of the *prima facia* obviousness of the combination. In addition, that one of skill in the art may need to perform experimentation to implement the combination is not evidence of non-obviousness, as long as only routine experimentation is required. Again, it must be noted that Applicant's mere allegation that actual experimentation would be required is not sufficient to overcome the *prima facia* showing of the prior art.

With regard to sensing of troponin-T antigen, Applicant notes that troponin-I and troponin-T are not chemically equivalent, and may not behave in the same way when modified. However, these differences would be recognized by one of skill in the art and, without evidence to the contrary, it is *prima facia* obvious that the person of skill would be able to account for these differences when designing the appropriate sensing molecules for the various analytes of interest.

Applicant makes various allegations that Examiner has relied upon hindsight or an obvious to try rationale. However, as clearly set forth in the rejections of record, the motivation to combine is found in the references themselves.

Applicant's remarks regarding the remaining combinations merely concern the alleged deficiencies addressed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric F Winakur
Primary Examiner
Art Unit 3768